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10/667,655	09/23/2003	Nyle S. Elliott	A-8601	9116

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HOFFMAN, WASSON & GITLER, P.C.
Suite 522
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Arlington, VA 22202

EXAMINER

MARCETICH, ADAM M

ART UNIT	PAPER NUMBER
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3761

MAIL DATE	DELIVERY MODE
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03/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/667,655

Applicant(s)

ELLIOTT, NYLE S.

Examiner

ADAM MARCETICH

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Agreement was reached in an interview 09 January 2008 to withdraw rejections under 35 USC § 103(a) over the combination of Millot in view of Brady. Finality of the previous Office Action mailed 22 October 2007 is withdrawn. See interview summary dated 09 January 2008.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 recites the limitation "said tube" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-3, 5-7, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Dyck (US Patent 6,350,255) in view of Johnson (US Patent 5,266,928).

8. Regarding claim 1, von Dyck discloses a device comprising:

a pad having an aperture (column 6, lines 17-27 and Fig. 2, combination of face plate 12 and catheter portion 14);

a plug (column 7, lines 8-12 and Fig. 2, closure member 18);

said plug removably secured to a pad (column 7, lines 21-24, and Fig. 2, closure member 18 appropriate for selectively openable sealing of aperture 24).

von Dyck discloses the invention as substantially claimed, see above. However, von Dyck lacks an alarm and first through fourth conductors as claimed [claim 1].

Johnson discloses:

an alarm attached to a pad (column 5, lines 7-14 and Fig. 3, electronic components 30);

a first and second conductor extending to an alarm (column 5, lines 14-20 and Fig. 3, spaced electrical contacts 33 and 34);

a third and forth conductor (column 4 and Fig. 2, spaced conductors 18 and 19). Johnson solves the problem of collecting or managing body waste while alerting a user. Johnson provides the advantage of alerting a user to the presence of body waste, especially individuals who lack the ability to appropriately respond to body sensations such as infants (column 3, lines 64-68 through column 4, lines 1-9). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of von Dyck as discussed with the alarm and conductors as taught by Johnson in order to alert a user.

Regarding the limitation of conductors extending to and from an aperture, Examiner notes that the scope of obviousness includes reshaping the conductive elements of Johnson in order to interface with the ostomy pad and plug of von Dyck. In other words, von Dyck provides the teaching of an ostomy pad and plug, while Johnson provides an alarm or alert device comprising conductors. According to the immediate specification, the presence of fecal matter completes an electric circuit and triggers an alarm (specification paragraph [0026]). Johnson uses the same approach, a change in resistance between conductors, to sense the presence of bodily wastes within a diaper (column 5, lines 55-67, change past pre-established resistance threshold). Therefore, modifying the structure of Johnson would have been obvious to fit the geometry of the ostomy pad and plug of von Dyck.

9. Regarding claims 2, 3 and 5, von Dyck discloses the invention as substantially claimed, see above. However, von Dyck lacks an alert device wherein the alarm emits an audible or visible alarm or transmits a signal to a remote location as claimed [claims 2, 3 and 5]. Johnson discloses an alert device wherein the alarm emits an audible or visible alarm or transmits a signal to a remote location (column 8, lines 1-13). Johnson provides the advantage of providing multiple channels to alert a caregiver or user. For example, a user with either impaired vision or hearing may rely more heavily on either audio or visual clues. Transmitting to a remote location provides the advantage of allowing caregivers to leave the user's immediate area. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of von Dyck as discussed with the alarms as taught by Johnson in order to effectively alert a caregiver or user.
10. Regarding claim 6, von Dyck discloses a plug is secured in an aperture by mating threads (column 7, lines 38-40 and Fig. 2, paired detent grooves 40).
11. Regarding claim 7, von Dyck discloses a pad made of a flexible, elastomeric material (column 6, lines 37-40, polyurethane).
12. Regarding claim 10, von Dyck discloses an absorbent sleeve disposed about a tube (column 13, lines 50-57 and Figs. 1-3, bolster 16 comprising foam surrounding catheter 14).
13. Regarding claim 11, von Dyck discloses a plug including a filter (column 8, lines 38-49, especially lines 47-49, filter (not shown) within port 52 of catheter 14).

14. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over von Dyck (US Patent 6,350,255) in view of Johnson (US Patent 5,266,928), further in view of Millot et al. (US Patent 6,171,289).

15. Regarding claim 4, von Dyck in view of Johnson discloses the invention as substantially claimed, see above. However, von Dyck in view of Johnson lacks a tactile alarm as claimed [claim 4]. Millot discloses a tactile alarm (column 2, lines 65-67 through column 3, lines 1-4 and column 4, lines 66-67, vibrator). Millot provides the advantage of alerting a user with visual or hearing impairment, a sleeping user, or providing a discreet alert. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of von Dyck in view of Johnson as discussed with the tactile alarm as taught by Millot in order to alert a user.

16. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over von Dyck (US Patent 6,350,255) in view of Johnson (US Patent 5,266,928), further in view of Kim (US Patent 5,569,216).

17. Regarding claim 8, von Dyck in view of Johnson discloses the invention as substantially claimed, see above. However, von Dyck in view of Johnson lacks an inflatable cuff as claimed [claim 8]. Kim discloses an inflatable cuff encircling a plug (column 2, lines 61-67 through column 3, lines 1-2 and Figs. 1-2, external balloon 100). Kim provides the advantage of preventing leakage of gases and liquids (column 1, lines

7-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of von Dyck in view of Johnson as discussed with the inflatable cuff as taught by Kim in order to prevent leakage.

18. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over von Dyck (US Patent 6,350,255) in view of Johnson (US Patent 5,266,928), further in view of McDonnell (US Patent 4,121,589).

19. Regarding claim 12, von Dyck in view of Johnson discloses the invention as substantially claimed, see above. However, von Dyck in view of Johnson lacks an adhesive ring as claimed [claim 12]. McDonnell discloses an adhesive ring attached to one side a pad (column 3, lines 54-56 and Fig. 1, adhesive material 9). McDonnell provides the advantage of providing additional sealing force between a user and waste collection device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of von Dyck in view of Johnson as discussed with the adhesive ring as taught by McDonnell in order to provide additional sealing force.

20. Claims 9 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Dyck (US Patent 6,350,255) in view of Johnson (US Patent 5,266,928), further in view of Brown (US Patent 5,036,859).

21. Regarding claims 9 and 21, von Dyck in view of Johnson discloses the invention as substantially claimed, see above. However, von Dyck in view of Johnson lacks

spaced-apart conductive rings and an upwardly extending section as claimed [claims 9 and 21]. Brown discloses:

third and fourth conductors each comprising a pair of spaced-apart conductors (column 7, lines 19-26 and Fig. 4 series of fingers 108a-b and 110a-b); and

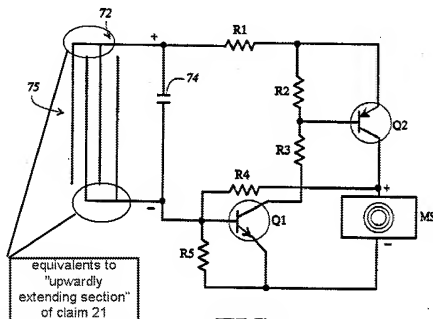
an upwardly extending section between conductors (Fig. 4, connections between successive fingers 108a-b and 110a-b).

Brown provides the advantage of increasing detector sensitivity (column 7, lines 35-43). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of von Dyck in view of Johnson as discussed with the conductors as taught by Brown in order to increase detector sensitivity.

Brown solves the problem of detecting moisture caused by waste material within a waste collection device, using paired conductors connected to an electronic alarm system. Placing paired, spaced conductors of the type used by both Johnson and Brown to detect waste material requires only slight changes to geometry when combined with a cylindrical plug. Therefore, changing the shape of electrodes 106 and 104 of Brown to ring-shaped is within the scope of obviousness.

Brown provides additional evidence in the form of electrode 150 (column 8, lines 6-9 and Fig. 6, electrode 150 having legs 156 and 158). Here is a further example of paired, spaced-apart electrodes provided in order to sense the presence of waste material and increase detector sensitivity.

Johnson provides additional examples of paired conductors and upwardly extending sections connected to an electronic alarm in Fig. 7 as annotated below. Again, ring-shapes are formed when conductors as discussed are wrapped within a cylindrical object.

**FIG 7**

Annotated Fig. 7 of Johnson

22. Regarding claim 22, von Dyck discloses a plug comprising a lumen having an outer surface and an inner surface (Figs. 2-3, closure member 18 depicted as comprising a lumen).

von Dyck in view of Johnson discloses the invention as substantially claimed, see above. However, von Dyck in view of Johnson lacks an upper ring extending about an outer surface and a lower ring extending about an inner surface as claimed [claim 22].

Brown discloses third and fourth conductors as discussed for claims 9 and 21 above, substantially forming rings when wrapped around the inside of a cylindrical lumen. Brown provides the advantage of increasing detector sensitivity and providing electrical continuity as discussed. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of von Dyck in view of Johnson as discussed with the electrodes as taught by Brown in order to increase sensitivity and provide electrical continuity.

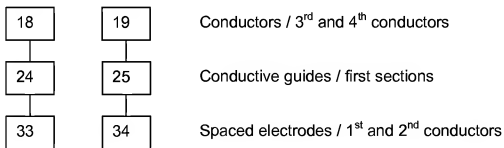
Examiner notes that placing electrodes within a lumen is necessary to sense the presence of waste material, since waste material approaches the inner space of closure member 18 as depicted in Fig. 3 of von Dyck. Likewise, placing contacts on the outside of closure member 18 is necessary in order to provide electrical continuity. A suitable connection pathway exists in closure member 18 of von Dyck (column 7, lines 24-27 and Fig. 3, vent hole 30).

23. Regarding claim 23, von Dyck discloses the invention as substantially claimed, see above. However, von Dyck lacks first and second conductors and first sections as claimed [claim 23]. Johnson discloses first and second conductors (column 5, lines 14-20 and Fig. 3, spaced electrical contacts 33 and 34), each comprising a first section extending from a circuit board to an interface (column 5, lines 21-31 and Fig. 3, conductive guides 24 and 25 connected to spaced electrical contacts 33 and 34 through barbs 26). Johnson provides the advantage of forming a connection between an alarm system and sensors. This connection is necessary in order to allow electronic components 30 of Johnson to detect the presence of waste material. Therefore, it would

have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of von Dyck as discussed with the first and second conductors and first sections as taught by Johnson in order to form an electrical connection.

Regarding the limitation of a "ring," Examiner notes that reshaping an electrode to fit around a plug is within the scope of obviousness as discussed for claims 9 and 21 above.

24. Regarding claim 24, von Dyck discloses the invention as substantially claimed, see above. However, von Dyck lacks first through fourth conductors as claimed [claim 24]. Johnson discloses first through fourth conductors as discussed for claims 1, 9 and 21 above. Johnson further discloses electrical continuity between spaced electrical contacts 33 and 34, conductive guides 24 and 25 and conductors 18 and 19 (column 5, lines 21-31). The following schematic further illustrates these connections:



25. Johnson provides the advantage of forming a connection between an alarm system and sensors as discussed for claim 23 above.

Response to Arguments

26. Applicant's arguments with respect to claims 1-12 and 21-23 filed 10 January 2008 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
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